Genesis Biosystems

JUN 20 2008

510(k) Summary of Safety and Effectiveness

Accela System

510(k) Number K 081578

Applicant:	Genesis Biosystems
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Contact Person:	Stephen J. MacDonald, Director of Compliance
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Date prepared:	01 / 16 / 2008
Device Trade Name:	Accela System
Common Name:	Intense Pulsed Light (IPL)
Classification Name:	Laser Surgical Instrument 21 C.F.R § 878.4810
Product Classification:	Class II device
Product Code:	GEX

Genesis
Biosystems

Legally Marketed Predicate Device: The Accela System is substantially equivalent in terms of technological characteristics, performance, intended use, indications for use and operator interface to;

- Chromogenex (K053324)
- Sciton (K032460)
- Lumenis (K020839)

System Description: The Accela is an Intense Pulsed Light-based medical device utilizing xenon flash lamp technology to illuminate the dermis to offer light based therapies as listed in the indications of use. The Accela emits *light at 400nm to 1200nm via a 50mm x 50mm treatment area at a repetition rate equal to or less than 0.5Hz (operator selective).
*Light is delivered to the skin surface, while cold air integrated through the handpiece, is provided to cool the epidermis.

Performance Standards: The device complies with the European Medical Directive 93/42/EEC concerning medical devices, and will comply with voluntary standards UL60601-1:1996 when marketed in the U.S.

Indications for use: Indications for Use for Fitzpatrick skin types (I to VI)

- The removal of unwanted hair and to effect stable long-term or *permanent hair reduction.
  Permanent hair reduction is defined as a long-term stable reduction in the number of hairs re-growing after a treatment regimen.
- The treatment of moderate inflammatory acne vulgaris
- The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, ephelides (freckles)
- The treatment of cutaneous lesions including warts, scars, and striae.
- The treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, erythema of rosacea, angiomas, and spider angiomas, poikiloderma of civatte, leg veins and venous malformations.

The integrated thermal cooling is indicated for use in cooling the epidermis at the treatment site prior to, during, and after light or laser treatment in general aesthetic dermatologic and plastic surgery procedures.

- Reduce pain during and/or with light or laser treatment (via partial anesthesia from cooling)
- Reduce discomfort during and/or associated with light or laser treatment
- Minimize thermal injury, including thermal necrosis, to non-target skin and skin structures during and/or associated with light or laser treatment, thus reducing possible complications such as scabbing, scarring, hyper – and/or hypopigmentation
- Allow the use of higher light or laser fluences for light or laser treatments (such as for hair removal and the treatment of vascular or pigmented lesions)
- Reduce potential side effects of light or laser treatments (such as for hair removal and the treatment of vascular or pigmented lesions)

Conclusion: The Accela system is substantially equivalent to its predicate devices cited above, based on predicate similarities. Despite the differences, the skin is treated in the same manner as the preidicate devices, Intense Pulsed Light and dermal cooling.

Similarities	**Lumenis Vasculite**	**Sciton BBL**	**Chromolight**
Output Spectrum Characteristics	Similar	Similar	Similar
Output Pulse Characteristics	Similar, Programmable	Similar, Programmable	Similar, Programmable
Treatment Parameters	Similar, Programmable	Similar, Programmable	Similar
Differences	**Lumenis Vasculite**	**Sciton BBL**	**Chromolight**
Output Light Delivery Method	Lightguide vs. Waveguide	Lightguide vs. Waveguide	Lightguide vs. Waveguide
Skin Cooling/Epidermal Coolong	Cold Gel vs. Cold Air	Gel, Contact vs. Cold Air	Contact vs. Cold Air
Skin Cooling Method	Conductive vs. Convective	Conductive vs. Convective	Conductive vs. Convective

Side Effects: In extreme cases, effects from treatment can include excessively red patches in the shape of the applicator head and blistering. If this occurs the tissue should be cooled and cared for as would normally be the case with burns to the skin, i.e. do not burst any blister formation, keep clean and covered until healed.

If blisters form, they are usually intra-epidermal in nature and heal without scarring. Inappropriate management of blisters during the healing stage will increase the chance of scarring.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Genesis Biosystems, Inc.
% Underwriters Laboratories, Inc.
Mr. Casey Conry
1285 Walt Whitman Road
Melville, NY 11741

JUN 20 2008

Re: K081578
Trade/Device Name: Accela System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: March 24, 2008
Received: June 5, 2008

Dear Mr. Conry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081578

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Prescription Use	X	AND / OR	Over-The-Counter-Use	
(Part 21 CFR 801 Subpart D)			(Part 21 CFR 801 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IS NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K081578